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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/182,645	10/30/1998	JIA-HE LI	23737	2236

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/182,645	LI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,28-31,35-39 and 46-49* is/are pending in the application.

4a) Of the above claim(s) *1-25,28-31 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-25, 28-31, 35-39 and 46-49 are pending in the application. Claims 1-25, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, and claims 28-31 and 35-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9 submitted on Feb. 1, 2000.

2. As instructed by the Board of Patent Appeals and Interferences for further consideration, following rejections are applied to claimed invention. Following the instruction from the board, the examiner considers the issue of whether the employment of a composition comprising the lignin herein for treating ischemia and/or reperfusion injury is anticipated and/ or obvious over the prior art, and without giving much patentable weight of functional interpretation, i.e., inhibiting PARG.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 46-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing the particular PARG inhibitors as discussed in the specification, e.g., pages 35-41, does not reasonably provide enablement for "PARG inhibitor" in general. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant uses functional limitation 'inhibitor of poly(ADP-ribose)glycohydrolase (PARG inhibitor)' to defined the agents employed in the method, without providing guidance, direction with respect to the structural features required to be a PARG inhibitor, and leave the search of PARG inhibitors other than those expressly disclosed herein a pure fishing expedition. A person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify those 'inhibitor of poly(ADP-ribose)glycohydrolase' within claimed scope. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: the vice of a functional claim exists not only when a claims is wholly functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty. Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate. Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first or second paragraph. Claims employing functional language at the point of novelty, such as Applicants, neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted *General Electric Company v. Wabash Appliance Corporation et* supra, at 468.

5. It is noted that the board states that due to the species election on the record, instant rejections are not ripe for consideration. The rejections are herein restated merely for compact prosecution, raising the issue of the examined claims in their full scope. However, in view the fact that the application discloses several groups of structurally distinct compounds as the PARG inhibitors (pages 26-31), further restriction may be necessary. The above rejections will be moot when the claims are restricted to a particular groups compounds disclosed herein.

Claim Rejection 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Wen et al. (of record), as evidenced by Tanuma (AB and AC), Barbour et al. (Bontany), and, with respect to claim 49, the definition of reperfusion injury.

7. Wen et al. treated gerbile with ischemia with ginseng powder (whole ginseng), in the amount of 0.6 to 1.5 g/kg/day. See, particularly, figure 2 at page 17. Tanuma teach that ginseng contains the lignin glycoside herein. See page 5, lines 2-4, in JP 3-205402 the translated copy. Therefore the claimed method herein read on the method taught by Wen et al. The PARG inhibitors, hydrolysable lignin and tanin, are inherently presented in whole ginseng materials Regarding the functional limitation about the detailed enzyme and biochemical function, i.e., inhibitor of poly(ADP-ribose) glycohydrase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. A

method known to be useful for treating the under lying etiology, would inherently be useful for treating the symptom caused by the etiology. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Regarding the effective amounts herein, note the effective amount of hydrolysable tannins or lignin glucoside is 0.1 to 100 mg/kg of body weight a day. See page 40, lines 12-15 in the specification. Further, it is noted the extract procedure employed by Tanuma is for physical separation and purification of the lignin glycoside and do not cause any chemical change of the components. Therefore, the purified final compound must presented in the original crude plant material. Furthermore, since lignin is a major component of plant materials (about 20 to 30% of cell walls, see page 64 of Botany), it would have reasonable expected that 1.5 g of whole ginseng root would contain more than 0.1 mg of the lignin herein. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § § 2112- 2112.02.

8. With respect to claim 49, which recites "reperfusion injury", it is noted that, for subject suffering cardiac or CNS ischemia, it is indistinguishable among those with injury from ischemia and those with injury from reperfusion, since ischemia is normally followed by reperfusion. See, definition of reperfusion injury attached herewith.

9. Claims 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (of record), as evidenced by Tanuma (AB and AC), and Barbour et al. (Bontany).

10. Kim et al. teaches a method of treating cardiac tissue damage results from ischemia and/or reperfusion by administering to rat with ginseng ethanol extract (100 mg/kg/day). Tanuma teach that ginseng contains the lignin glycoside herein. See page 5, lines 2-4, in JP 3-205402 the translated copy. It is also noticed that both ethanol soluble and ethanol insoluble lignin glycosides are PARG inhibitors. See, JP3-205402, example 1 at page 6 (precipitation with ethanol) for ethanol insoluble, and JP 4-13684, example 1, (adding ethanol, the compound remains in the solution). Therefore the claimed method herein read on the method taught by Wen et al. The PARG inhibitors, hydrolysable lignin and tannin, are inherently presented in the ginseng extract of KIM. Regarding the functional limitation about the detailed enzyme and biochemical function, i.e., inhibitor of poly(ADP-ribose) glycohydrase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. A method known to be useful for treating the under lying etiology, would inherently be useful for treating the symptom caused by the etiology. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Regarding the effective amounts herein, note the effective amount of hydrolysable tannins or lignin glucoside is 0.1 to 100 mg/kg of body weight a day. See page 40, lines 12-15 in the specification. Furthermore, since lignin is a major component of plant materials (about 20 to 30% of cell walls, see page 64 of Botany), it would

have reasonably expected that the ethanol extract of Kim would contain significant amount of lignin. Further, it is noted the extract procedure employed by Tanuma is for physical separation and purification of the lignin glycoside and do not cause any chemical change of the components. Therefore, the purified final compound must present in the original crude plant material. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § § 2112- 2112.02.

Claim Rejections 35 U.S.C. 103

a. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wen et al. (of record), as evidenced of Tanuma (AB and AC) Barbour et al. (Botany), and, with respect to claim 49, the definition of reperfusion injury.

12. Wen et al. teach that Ginseng is useful in protection neuronal loss resulted from ischemia. See the abstract. Wen further teaches that whole ginseng material, red ginseng powder (RGP) is more effective than crud ginseng saponin (CGS), which is better than purified saponin (Rb1, Rg1 or Ro). See, figure 2 at pages 17. The amount of whole ginseng material (RGP) employed is about 0.6 to 1.5 g/kg/day. (figure 2).

13. Tanuma teach that ginseng contains the lignin glycoside herein. See page 5, lines 2-4, in JP 3-205402 the translated copy. Regarding the functional limitation about the detailed enzyme and biochemical function, i.e., inhibitor of poly(ADP-ribose) glycohydrase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. A method known to be useful for treating the under lying etiology, would inherently be useful for treating the symptom caused by the etiology. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

14. Wen et al. do not teach expressly treating a patient how suffering CNS ischemia (e.g., stroke).

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ whole ginseng for treating patients suffering from CNS ischemia.

15. A person of ordinary skill in the art would have been motivated to employ whole ginseng for treating patients suffering from cardiac or CNS ischemia because ginseng is known to provide protection from neuronal loss. Further, one of ordinary skill in the art would be motivated to chose the whole ginseng over the particular known ginseng saponin since whole ginseng provide better result. With respect to claim 49, which recites "reperfusion injury", it is noted that, for subject suffering cardiac or CNS ischemia, it is indistinguishable among those

with injury from ischemia and those with injury from reperfusion, since ischemia is normally followed by reperfusion. See, definition of reperfusion injury attached herewith.

16. Regarding the effective amounts herein, note the effective amount of hydrolysable tannins or lignin glycoside is 0.1 to 100 mg/kg of body weight a day. See page 40, lines 12-15 in the specification. Further, it is noted the extract procedure employed by Tanuma is for physical separation and purification of the lignin glycoside and do not cause any chemical change of the components. Therefore, the purified final compound must present in the original crude plant material. Furthermore, since lignin is a major component of plant materials (about 20 to 30% of cell walls, see page 64 of Botany), it would have reasonable expected that 1.5 g of whole ginseng root would contain more than 0.1 mg of the lignin herein. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § § 2112- 2112.02.

17. Claims 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (of record), as evidenced of Tanuma (AB and AC), and Barbour et al. (Botany).

18. Kim et al. teaches that Ginseng ethanol extract is effective in protection heart from ischemia-reperfusion condition in the amount of 100 mg/kg/day. See, the abstract. Tanuma teach that ginseng contains the lignin glycoside herein. See page 5, lines 2-4, in JP 3-205402 the translated copy. It is also noticed that both ethanol soluble and ethanol insoluble lignin glycosides are PARG inhibitors. See, JP3-205402, example 1 at page 6 (precipitation with ethanol) for ethanol insoluble, and JP 4-13684, example 1, (adding ethanol, the compound

remains in the solution). Therefore, the ethanol extract disclosed by Kim would have reasonably expected to contain substantial amounts (more than1%) of lignin. Therefore the claimed method herein read on the method taught by Wen et al. The PARG inhibitors, hydrolysable lignin and tannin, are inherently presented in the ginseng extract of KIM. Regarding the functional limitation about the detailed enzyme and biochemical function, i.e., inhibitor of poly(ADP-ribose) glycohydrase, it is well-settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. A method known to be useful for treating the under lying etiology, would inherently be useful for treating the symptom caused by the etiology. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Regarding the effective amounts herein, note the effective amount of hydrolysable tannins or lignin glycoside is 0.1 to 100 mg/kg of body weight a day. See page 40, lines 12-15 in the specification. Furthermore, since lignin is a major component of plant materials (about 20 to 30% of cell walls, see page 64 of Botany), the ethanol extract of Kim would have reasonably expected to contain significant amount of lignin. When the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § § 2112- 2112.02.

Remarks

Applicants remarks about the particular extract procedure of Tanuma reference have been fully considered, it is noted that the procedure is for large scale extraction, which is obvious to use minimum amount of solvent. It is noted that the extract procedure involves "extract" (soaking) the material in ethanol at room temperature before extracting the lignin compounds. It is understood that such soaking would not remove significant amount of the lignin. It should be understood that ethanol extract in Kim et al. is not just soaking, but to extract any thing soluble in ethanol. As indicated in Tunuma (4-13684) reference, the lignin soluble in ethanol has PARG inhibiting active.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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